



January 21, 2005

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Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810),
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Brush Pkwy.
College Park, MD 20740

JAN 31 2005

Section 403(r) (6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r) (6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

Joint Lubricant™

Optimum Joint Health

Contains Fast Absorbing Powerful Nutrients

- Hyaluronic Acid†
- Collagen†
- Supports Joint Cushioning
- Lessens Stiffness‡

With age, the ability to produce some of the nutrients necessary for joint function and cartilage building declines, making it difficult to supplement what is lost to maintain adequate joint strength, cushioning and structure.

Joint Lubricant™ contains the powerful nutrients Collagen and Hyaluronic Acid. These add a super lubricant to the joint tissues to promote mobility and comfort.

This unique science based formulation combines the joint health benefits of Glucosamine and Chondroitin with the powerful nutrients, Collagen and Hyaluronic Acid, found in Joint Lubricant™. Joint Lubricant™ provides joint lubrication and increased comfort. Glucosamine has been shown to help renew cartilage and joint tissue. These ingredients work together to promote joint strength, flexibility and mobility.

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Joint Lubricant™ adds a super lubricant to the joint tissues to promote mobility and comfort.

Collagen is the most plentiful protein and building block in the body shown to regenerate joint tissue.

Hyaluronic Acid declines with age and is critical to maintain joint strength, cushioning and structural integrity.

A powerful joint complex that contains unique ingredients for optimum Joint Health.

†Hyaluronic acid and Collagen are fast absorbing in the blood and thus available for joint tissues.

‡Associated with daily overexertion and when used as a long-term approach to improved mobility.

on the following product:

Your Life® Glucosamine Chondroitin Plus Joint Lubricant™

Very truly yours,

Leiner Health Products

Kristi Ansnes

Regulatory Affairs Associate



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Food and Drug Administration
(Continued)

The following brands also use the above statement:

Albertson's
BI-MART
BIO BALANCE®
COUNCIL LABS®
CVS®
ECKERD®
equate®
Hannaford®
HealthLine
health PRIDE
Kash n' Karry
KIRKLAND Signature™
Kroger®
Longs
MARC'S
Member's Mark
MEIJER™

Nature's Origin®
NATURE'S VALLEY™
NATURITE®
NUTRA CHOICE
NUTRI-BLEND
PHARMACIST FORMULA®
SAFEWAY SELECT™
Sav-On™
Shaw's
ShopKo®
Spring Valley®
TARGET®
TOP CARE®
TRUNATURE®
Wegmans®